October 24, 2016

B. Vindell Washington, MD, MHCM, FACEP
Coordinator
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
Hubert Humphrey Building, Suite 729
200 Independence Avenue SW Washington, DC 20201

Submitted electronically to: http://www.regulations.gov

Dear Dr. Washington:

Health Level Seven (HL7) International welcomes the opportunity to submit comments on the current draft of ONC's 2017 Interoperability Standards Advisory (Advisory). HL7 is a not-for-profit, ANSI-accredited standards developing organization dedicated to providing a comprehensive framework and related interoperability standards, including the rapidly emerging Fast Healthcare Interoperability Resources (FHIR), the Consolidated Clinical Document Architecture (C-CDA), and the widely used V2 messaging standards. HL7 is comprised of more than 1,600 members from over 50 countries, including 500+ corporate members representing healthcare providers, government stakeholders, payers, pharmaceutical companies, vendors/suppliers, and consulting firms.

As the global authority on interoperability in healthcare, HL7 is a critical leader and driver in the standards arena. The products of our organization – including the rapidly evolving FHIR standards - provide the underpinnings for connected, patient-centered health care and an information highway for precision medicine.

Key high-level comments include the following:

- **References to Implementation Guides -** In comments on previous editions of the ISA, HL7 has encouraged references to specific implementation requirements rather than foundational standards. We therefore appreciate the increased reference to implementation guides proposed for the 2017 edition.

- **Maturity of FHIR Specifications and Implementation Guides -** We appreciate the recognition of FHIR as a rapidly emerging standard and note that, in many cases, only the core FHIR standard is referenced because there may, as yet, be no FHIR implementation guide available or in development for the interoperability need at hand. We note though that implementation guides specific to these interoperability needs are emerging in the short term to be considered for next year's version (e.g., Argonaut's efforts are being balloted using FHIR STU 3). When there is not yet any implementation guidance, we suggest that the ISA more clearly indicate that:

  1) Implementers should recognize implementation guides will become available over time;
  2) Adjustments may be required to the implementations already coded;

  Implementers should also be encouraged to participate and contribute to emerging implementation guides sooner to avoid widely different interpretations of the same standard for the same use case, such as what happened with HL7 V2, V3, and CDA.

- **Clarification on Additional Standards -** We are concerned that as the number of use cases, standards, implementation specifications and emerging implementation specifications covered by the ISA grows, it is not sufficiently clear to the reader that there is no expectation that any single EHR or other HIT solution is expected to implement all of the identified interoperability standards, rather than those specifically required for relevant use cases supported by the EHR or other HIT solution. We suggest that this point be made clearer.

- **Use Cases and Interoperability Need -** We suggest that the use cases could be clearer and that having a paragraph for each interoperability need would provide the context that a simple title cannot always convey. This context is necessary to understand fit-for-purpose of the standard, as well as adoption level and maturity. Such a paragraph could clarify whether the setting is, e.g., inpatient vs. ambulatory, mobile, all the above, etc. which further can assess whether it either is applicable as a reviewer, or suggested as an implementer.

- **Linking In Development Standards and Pilots -** We appreciate the introduction of standards marked "In Development" to improve focus on emerging standards and better address standards process maturity. To further encourage participation in developing and piloting standards marked as such, we suggest that the ISA highlight that these standards -- in particular -- would benefit from lessons learned in development and pilots, more so than attempts to implement them widely. Implementing immature standards too early and too widely, particularly in the absence of clear, unambiguous implementation guidance, will yield too many missed expectations.

- **Providing Feedback and Rational to Commenters -** We provided substantial feedback in response to the 2016 ISA's request for input on the 2017 ISA. A number of our comments were not reflected or addressed in the draft 2017 ISA. It would be very helpful for ONC to provide feedback/rationale to the commenters (and the broader group of ISA users) on why comments were not accepted. After review with the various HL7 workgroups that contributed to these comments and considering the updates already made, HL7 decided to resubmit a number of those comments, clarifying them and/or updating them where needed.

Attached we provide further detailed comments in context of the 2017 ISA sections.

Should you have any questions about our attached comments, please contact Charles Jaffe, MD, PhD, Chief Executive Officer of Health Level Seven International at cjaffe@HL7.org or 734-677-7777. We look forward to continuing this discussion and offer our assistance to ONC.

Sincerely,

Charles Jaffe, MD, PhD
Chief Executive Officer
Health Level Seven International

Patricia Van Dyke
Board of Directors, Chair
Health Level Seven International

Detailed Comments

Introduction

- Scope
    - While it is appropriate to address the wider HIT interoperability capabilities in support of clinical use cases, it is not always clear what specific HIT capabilities are applicable for certain interoperability standards. For example, the introduction of the research focused interoperability standards may give the impression that all EHRs or similar HIT should support that standard. However, care must be taken to not encumber all interoperability capabilities on all variants of HIT and to avoid putting unnecessary burden on the primary users/clinicians of those systems. To that end, we suggest to provide categorization of use cases and provide more detail on the intent of the use case to help the reader come to these conclusions. E.g., add a paragraph to each use case beyond a title.
    - We also suggest that ONC clarify that the focus is on inter-provider/organizational interoperability, not intra-provider/organizational interoperability, unless there is a plan to include specific standards for those use cases, e.g., Lab Orders within Hospitals (V2.x), Pharmacy Orders within Hospitals (V2.x).

- Purpose
    - We are concerned that the ISA is not more closely tied to the Certification Edition in terms of expected adoption into a future certification edition. Is the intent that the ISA replaces the Certification Edition? If not, the relationship should be clarified as it will otherwise remain confusing. If it is the intent, expectations would have to be set what the thresholds would be for adoption and associated timelines, which we do not believe to be the intent of the ISA.
    - We suggest that further clarification is needed on how best to use the ISA. This, in combination with the filtering capabilities suggested below, may make this document more useful. This is especially true considering the average standards expert already knows this and the average implementer does not know what to act on, how, or when.

- ISA Structure
    - The new category "In Development" provides better categorization of the current state of a standard and allows for inclusion of promising, new standards on the horizon. This area in particular could yield more standards that would support the same use case. In that situation we suggest, that the ISA, not pick winners yet based on incomplete information and err on the side of including those variants. For example, the ISA could list both DAF efforts in HL7 and IHE, not just one or the other, until adoption levels and experience clearly favor one or the other.
    - As part of defining "In Development" we suggest to clarify that standards such as FHIR experience early and wide use, not only in proof of concepts and pilots, but also in early production environments. We encourage early participation to enhance the maturity of these standards through actual use.
    - We note that Adoption Level and Implementation Maturity may vary based on the environment/setting in which the standard is deployed. As they are presented, the current ratings assume the traditional in-house "EHR" space. As new interoperability needs and standards are identified for mobile/consumer use cases, additional ratings should be given to account for newer classes of Adoption and Maturity in mobile and consumer settings. For example, HL7 v2 and CDA are widely adopted and mature in EHRs, but to a lesser extent in mobile health. Certain standards may be too heavy weight for mobile adoption, especially in situations where bandwidth is limited, and thus will never get widely adopted in that environment. This information can be contained in the use case paragraph as suggested earlier, and possibly result

in splitting the interoperability need into two or more parts to better document the Adoption Level, Implementation Maturity, Federally Required, and Test Tool Availability.

Additionally, we suggest the application of these adoption status codes needs to be clarified. Are they intended to indicate the extent to which software developers have adopted a standard or implementation specification by having corresponding capability available? Or do they indicate whether such capability is actually deployed for use by providers, HIEs, etc. or the extent to which the breadth of requirements in a standard or implementation specification are covered or a combination of these factors? Some assertions may need to be adjusted accordingly

o Organizing the standards and implementation specifications based on Use Case and Interoperability Needs should provide more helpful context to assess fit-for-purpose and maturity. As indicated earlier, certain standards may be applicable in one setting, but not another, or more mature for one use case rather than another. However, in a number of situations, e.g., Care Plan, it is unclear what the intended use case is that the interoperability need applies to, and what the difference is between a use case and interoperability need. We request that ONC clearly define the difference between the two, and provide for at least each use case header a short description of what the scope of the use case that is being considered for the suggested standard or implementation specification.

o Various standards were proposed for the 2015 Edition but did not get included in the final rule, and they did not make it in the Advisory either, e.g., esMD. HL7 believes that the Advisory should over time become a predictor of what will be endorsed for national adoption. Therefore, we suggest that the Advisory consider the various standards that did not make it into the 2015 Edition if they are still on the ONC "roadmap, or clarify that they are no longer being considered.

o We appreciate the inclusion of links to the Interoperability Proving Ground to more closely tie projects to the standards being used. We suggest that the Interoperability Proving Ground similarly should link back for each topic which standards / implementation guides from the ISA were actually used and clarify any variances (e.g., extensions).

o With the migration to a web based publishing approach we suggest providing more filtering capabilities to enable implementers to identify standards that are present in federal regulations, are under development and/or are widely adopted (e.g., 3 bullets or more). This will be helpful in decision making to invest in deployment, putting them on a watch list, or engaging in the development/initial rollout of the standard. The current format remains overwhelming and difficult to navigate to what is relevant to "me".

Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications

- Harmonization of vocabulary and terminology continues to be a challenge, particularly with the inclusion of additional standards. HL7 stands ready to work with ONC and other SDOs to harmonize use of vocabularies and terminologies not only within certain standards, but across standards as well to achieve more comprehensive semantic interoperability.
- We suggest that, while the vocabulary and terminology referenced are listed for a use case in general, implementation guides typically provide more specific guidance on what vocabulary is to be used for each field or context. Such guidance overrides the more general references in Section I.
- While many vocabulary standards may be applicable across all contexts, some may need adjustment when used in the consumer/mobile context. Consumer friendly vocabularies may be needed, with standardized mappings to/from clinical vocabularies like SNOMED-CT, LOINC, RxNorm. HL7 suggests adding these as they become available, to each Interoperability Need in the Vocabulary Section of the ISA.

- I-A: Allergies
    - Interoperability Need: Representing Patient Allergic Reactions
        - No comment
    - Interoperability Need: Representing Patient Allergens: Medications
        - RxNorm: We suggest clarifying whether RxNorm refers to RxNorm as the source or whether other sources are included with the RxNorm download.
        - We suggest to remove UNII and NDF-RT since SNOMED is present.
        - For Applicable Value set we suggest to use a constrained list of RxNorm (just ingredient or perhaps with MIN) and SNOMED. The HL7 Patient Care Workgroup would be able to assist with arriving at an appropriate subset.
    - Interoperability Need: Representing Patient Allergens: Food Substances
        - We suggest to remove UNII and NDF-RT since SNOMED is present.
    - Interoperability Need: Representing Patient Allergens: Environmental Substances
        - No comment

- I-B: Encounter Diagnosis
    - Interoperability Need: Representing Patient Medical Encounter Diagnosis
        - No comment
    - Interoperability Need: Representing Patient Dental Encounter Diagnosis
        - No comment

- I-C: Family Health History
    - Interoperability Need: Representing Patient Family Health History
        - No comment
    - Interoperability Need: Representing Patient Family Health History Observations
        - No comment

- I-D: Functional Status/Disability

- o Interoperability Need: Representing Patient Functional Status and/or Disability
  - ▪ We recommend considering PROMIS, acknowledging it is not an official standard and comes with the associated risk. Standards not maintained by an SDO or similar organization increases risks for implementers. While appropriate experts have developed many standards with the best of intentions, failure to move such standards into formal SDO organizations and processes leaves the standards without a clear plan for ongoing maintenance, update, and support. However, we still suggest including this standard where ONC can clearly identify that it is not under active maintenance by a formal SDO, and should clearly state the risks to implementers.

- • I-E: Health Care Provider
  - o Interoperability Need: Representing Care Team Member (Health Care Provider)
    - ▪ No comment
  - o Interoperability Need: Representing Provider Role in Care Setting
    - ▪ We recommend removing "HL7 Participation Function", restrict to the following SNOMED-CT® concepts and their children:
      - • 429577009   Patient Advocate
      - • 223366009   Healthcare professional
      - • 394730007   Healthcare related organization

- • I-F: Imaging (Diagnostics, interventions and procedures)
  - o Interoperability Need: Representing Imaging Diagnostics, Interventions and Procedures
    - ▪ We suggest that the expected timeframe for Radlex to be incorporated into LOINC be explicitly noted. Our understanding is that this is expected to be completed in Sept. 2017. What should be used prior to that time should also be specified.
    - ▪ It is not clear which vocabulary within DICOM is being referenced. We suggest that all references can be done using an OID to the valueset and preferably exists within VSAC.

- • I-G: Immunizations
  - o Interoperability Need: Representing Immunizations – Historical
    - ▪ We suggest MVX be reclassified from HISTORICAL representation to ADMINISTERED representation
  - o Interoperability Need: Representing Immunizations – Administered
    - ▪ We also suggest RXNORM be added as another code set standard to represent ADMINISTERED data.
    - ▪ We suggest a comment note be added under Limitations for National Drug Code, regarding the issue of which Bar Code to use when there are multiple active ingredients in a single package, or multiple separate ingredients that need to be mixed together
    - ▪ We suggest that the adoption level of the National Drug Code for Immunizations is much lower than indicated. Most exchanges use the

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CVX/MVX code sets for both new and historical immunizations and the IIS community has consistently pushed back on this requirement.

- I-H: Industry and Occupation
    - o Interoperability Need: Representing Patient Industry and Occupation
        - ▪ In the limitations, Dependencies box we recommend the following changes/corrections:
            - The text "Industry and Occupation Computerized Coding System" should be replaced with "CDC Census Coding System" which is the one being recommended by NIOSH and which is structure more in line with job classifications; Federal agencies are required to use standard classifications (such as North American Industry Classification System) and the Standard Occupation Classification System. Recommend that ONC replace NIOCCS with CDC Census Coding System.
            - Also, NUCC and its Health Care Taxonomy code standard is not an appropriate reference here, since that code set is a classification of health profession specialties (medical, nursing, etc) and NOT an occupation classification system. Recommend to delete this reference.
            - Lastly, a note should be made that while there are international classifications of occupation, they are not as granular as the one being referenced by NIOSH (CDC_Census) for use in the US.

- I-I: Lab tests
    - o Interoperability Need: Representing Laboratory Tests
        - ▪ We suggest to remove the second bullet in the Limitations sections as the third bullet already better describes the options in production.

- I-J: Medications
    - o Interoperability Need: Representing Patient Medications
        - ▪ No comment

- I-K: Numerical References & Values
    - o Interoperability Need: Representing Units of Measure (For Use with Numerical References and Values)
        - ▪ No comment

- I-L: Nursing
    - o We appreciate the harmonization under SNOMED.
    - o Interoperability Need: Representing Nursing Assessments
        - ▪ No comment
    - o Interoperability Need: Representing Nursing Interventions

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- New section: Sensitive Condition Codes
- Have one general new section, while include references to that section from other places, e.g., Medications, Conditions, etc.
  - Interoperability Need: Representing Outcomes for Nursing
    - No comment
  - Interoperability Need: Representing Patient Problems for Nursing
    - No comment
  - Interoperability Need: Representing Nursing Interventions and Observations (Observations are Assessment Items)
    - No comment

- I-M: Patient Clinical "Problems" (i.e., conditions)
  - Interoperability Need: Representing Patient Clinical "Problems" (i.e., Conditions)
    - Many systems capture/document conditions in other code sets – ICD-9/ICD-10. We suggest these other standards be recognized for current use (e.g., ICD-10) or as part of historical analysis/analytics/CDS (e.g., ICD-9). Similarly, for reporting HEDIS Quality Measures, SNOMED equivalents are not provided. Rather code sets such as ICD and CPT are used.
    - We note that the link to LOINC projects in the Limitations section actually goes to the full list of projects, not just LOINC projects.

- I-N: Preferred Language
  - Interoperability Need: Representing Patient Preferred Language (Presently)
    - We are concerned that RFC 5646 represents a syntax, not a code system per se, therefore it is difficult to express in most interoperability standards where language would reference a specific code system (e.g.,. ISO 639) rather a syntax

- I-O: Procedures
  - Interoperability Need: Representing Dental Procedures Performed
    - No comment
  - Interoperability Need: Representing Medical Procedures Performed
    - No comment

- I-P: Race and Ethnicity
  - Interoperability Need: Representing Patient Race and Ethnicity
    - No comment

- I-Q: Research
  - Interoperability Need: Representing Analytic Data for Research Purposes
    - No comment

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- I-R: Sexual Orientation and Gender Identity
  - Interoperability Need: Representing Patient Gender Identity
    - No comment
  - Interoperability Need: Representing Patient Sex (At Birth)
    - No comment
  - Interoperability Need: Representing patient-identified sexual orientation
    - No comment

- I-S: Social Determinants [See Questions 10 and 11, Section IV]
  - Interoperability Need: Representing Financial Resource Strain
    - It is unclear why the adoption level is 5. While LOINC as a code set is generally and widely adopted, this status is not necessarily the same for each use case, e.g., this one.
    - We suggest splitting this line into a Standard for Question and Standard for Answer to be consistent with other vocabulary entries, even if the standards referenced may be the same.
    - We note that depending on clinical use cases different assessment scales may be used making it challenging to arrive at one single, national assessment scale at this time. What efforts are in place to harmonize across these assessments?
  - Interoperability Need: Representing Level of Education
    - It is unclear why the adoption level is 5. While LOINC as a code set is generally and widely adopted, this status is not necessarily the same for each use case, e.g., this one.
    - We suggest splitting this line into a Standard for Question and Standard for Answer to be consistent with other vocabulary entries, even if the standards referenced may be the same.
    - We note that depending on clinical use cases different assessment scales may be used making it challenging to arrive at one single, national assessment scale at this time. What efforts are in place to harmonize across these assessments?
  - Interoperability Need: Representing Stress
    - It is unclear why the adoption level is 5. While LOINC as a code set is generally and widely adopted, this status is not necessarily the same for each use case, e.g., this one.
    - We suggest splitting this line into a Standard for Question and Standard for Answer to be consistent with other vocabulary entries, even if the standards referenced may be the same.
    - We note that depending on clinical use cases different assessment scales may be used making it challenging to arrive at one single, national assessment scale at this time. What efforts are in place to harmonize across these assessments?
  - Interoperability Need: Representing Depression
    - We recommend changing applicable value set to only LOINC® observation codes belonging to LOINC® panels:

- 44249-1 - This encompasses all questions and answers in the standard PHQ-9 assessment, and the PHQ score.
- 69724-3 – PHQ-4
- 55757-9 – PHQ-2
  - It is unclear why the adoption level is 5. While LOINC as a code set is generally and widely adopted, this status is not necessarily the same for each use case, e.g., this one.
  - We suggest splitting this line into a Standard for Question and Standard for Answer to be consistent with other vocabulary entries, even if the standards referenced may be the same.
  - We note that depending on clinical use cases different assessment scales may be used making it challenging to arrive at one single, national assessment scale at this time. What efforts are in place to harmonize across these assessments?
- o Interoperability Need: Representing Physical Activity
  - It is unclear why the adoption level is 5. While LOINC as a code set is generally and widely adopted, this status is not necessarily the same for each use case, e.g., this one.
  - We suggest splitting this line into a Standard for Question and Standard for Answer to be consistent with other vocabulary entries, even if the standards referenced may be the same.
  - We note that depending on clinical use cases different assessment scales may be used making it challenging to arrive at one single, national assessment scale at this time. What efforts are in place to harmonize across these assessments?
- o Interoperability Need: Representing Alcohol Use
  - It is unclear why the adoption level is 5. While LOINC as a code set is generally and widely adopted, this status is not necessarily the same for each use case, e.g., this one.
  - We suggest splitting this line into a Standard for Question and Standard for Answer to be consistent with other vocabulary entries, even if the standards referenced may be the same.
  - We note that depending on clinical use cases different assessment scales may be used making it challenging to arrive at one single, national assessment scale at this time. What efforts are in place to harmonize across these assessments?
- o Interoperability Need: Representing Social Connection and Isolation
  - It is unclear why the adoption level is 5. While LOINC as a code set is generally and widely adopted, this status is not necessarily the same for each use case, e.g., this one.
  - We suggest splitting this line into a Standard for Question and Standard for Answer to be consistent with other vocabulary entries, even if the standards referenced may be the same.
  - We note that depending on clinical use cases different assessment scales may be used making it challenging to arrive at one single, national assessment scale at this time. What efforts are in place to harmonize across these assessments?

- o Interoperability Need: Representing Exposure to Violence (Intimate Partner Violence)
    - It is unclear why the adoption level is 5. While LOINC as a code set is generally and widely adopted, this status is not necessarily the same for each use case, e.g., this one.
    - We suggest splitting this line into a Standard for Question and Standard for Answer to be consistent with other vocabulary entries, even if the standards referenced may be the same.
    - We note that depending on clinical use cases different assessment scales may be used making it challenging to arrive at one single, national assessment scale at this time. What efforts are in place to harmonize across these assessments?
    -
- I-T: Tobacco Use (Smoking Status) [See Question 12, Section IV]
    - o Interoperability Need: Representing Patient Tobacco Use (Smoking Status) Observation Result Values or Assertions
        - No comment

- I-U: Unique Device Identification
    - o Interoperability Need: Representing Unique Implantable Device Identifiers
        - We note that the UDI regulation by the FDA is actually not an interoperability standard and should not be listed as such. Rather it defines what a UDI is and prescribes the need for capturing and presenting such data.

          There is ongoing confusion about how and when to communicate UDI, and we are concerned that there is a rush to implement UDI exchange without full consideration of all relevant uses and requirements. At a minimum, all care related and downstream-related uses need to be considered together to ensure appropriate data capture and communication can occur. The HL7 Harmonization Pattern for Unique Device Identifiers has recently undergone an update (the URL provided in the 2017 ISA is out of date), while a project has been established to fully define the various interoperability use cases where HL7 needs to provide further guidance on when and how to communicate UDI using V2, C-CDA, and/or FHIR in particular. We further note that additional requirements have emerged to not only be able to communicate the UDI carrier (the human readable formatted string under the barcode on the device), but also the individual UDI components represented in the UDI carrier. This particularly requires C-CDA updates as it currently is not formally capable of doing so. Therefore, while per the definition of Standards Process Maturity one could state the document is "final", the impression that all the necessary standards and implementation guides are in place is not accurate. Additionally, we expect non-HL7 standards to be able to communicate the UDI carrier and/or the individual UDI components as well, which should be reflected here. As a minimum, we suggest describing these gaps in the Limitations, Dependencies, and Preconditions for Consideration section until the relevant implementation guides emerge.

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In addition, it will be important to consider the applicability of unique device identification to non-implanted mobile healthcare devices and general consumer devices performing healthcare functions (e.g., smartphones). There is a definite need to capture the chain of data custody from the originating device as the data flows from device to other HIT including EHRs. The concept of both hardware and software as "devices" and as "authors/actors" is already supported in HL7 standards such as V2, C-CDA and FHIR, so these capabilities should be extended to support device identification for mobile health. A key question is whether UDI, or something like it, should be assigned to such devices and/or to each medical app that is installed on such devices? It has also been suggested that UDI-DI 22| should be updated for each major revision to medical app software, and UDI-PI should be updated for each minor software revision. It is too soon to say definitively whether UDI is the appropriate standard, given the current focus of UDI on implanted devices, but the need for an interoperable standard to identify mobile devices exists. See also suggestions for Data Provenance, which device identification would support. If UDI is found to be appropriate for mobile device/app identification, it should be represented consistently across Standards as will be proposed in the HL7 document: "Harmonization Pattern for Unique Device Identifiers."

As we develop the use cases and supporting implementation guidance for interoperability, we suggest separating at least the use cases focusing on logistics (from manufacturer to provider) from the clinical use (implantation and/or monitoring and actual use) flows where UDI needs to be exchanged. While there is a connection point, requirements may vary, as well as keep the guidance more manageable.

- I-V: Vital Signs
    - Interoperability Need: Representing Patient Vital Signs
        - No comment

- Other Vocabulary
    - We propose that the ISA add HL7 Privacy and Security Healthcare Classification System [HCS] – HL7 and its Security and Community Based Collaborative Care (CBCC) Work Groups recommend that the ISA include the normative HL7 Privacy and Security Healthcare Classification System [HCS] because it encompasses vocabulary for the confidentiality Code that is required for use in:

- All CDA Implementation Guides at the Document Header, and may be used at the Section level because it is required in the base CDA R2 standard;
- The IHE XDS Soap Headers required by Meaningful Use, which must include at least the confidentialityCode and may include other HCS vocabulary for e.g., purpose of use and obligations1
- The Direct XDR/XDM option for Meaningful Use, which must include at least the confidentialityCode and may include other HCS vocabulary for e.g., purpose of use and obligations; and
- Data Segmentation for Privacy, which, like all CDA profiles, requires confidentialityCode at the Document Header, recommends it at the Section level, recommends inclusion of a Privacy Marking section for security labels pertaining to the entire Document, and recommends inclusion in Privacy Annotations or Security Labels at the CDA Entry Level.

In addition, it is used in the draft FHIM Privacy and Security Architecture Framework, which is updating the expired HL7 Security and Privacy Domain Analysis Model. For these reasons, the HL7 and its Security and CBCC Work Groups support the ISA recommending increasing the adoption level to at least 61% to 80% adoption and to indicate that the specification has been adopted indirectly because DS4P, Exchange, and Direct XDR/XDM are adopted in regulation. These recommendations are captured below in an ISA table.

Interoperability Need: Representing privacy and security classification of healthcare information

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[1] IHE IT Infrastructure Technical Framework, Volume 3 (ITI TF-3): Cross-Transaction and Content Specifications Rev. 11.0 Final Text – 2014-09-23 p.62
4.2.3.2.5 DocumentEntry.confidentialityCode
Description:
The code specifying the security and privacy tags of the document. These codes are set by policy of the participants in the exchange, e.g., XDS affinity domain. confidentialityCode is part of a codification scheme. The confidentialityCode can carry multiple vocabulary items. HL7 has developed an understanding of security and privacy tags that might be desirable in a Document Sharing environment, called HL7 Healthcare Privacy and Security Classification System (HCS). The following specification is recommended but not mandated by IHE, as the vocabulary bindings are an administrative domain responsibility.
Each confidentialityCode is coded within an ebRIM Classification object. See Section 4.2.3.1.2 for a description of coding an ebRIM Classification. There shall be zero or more ebRIM Classification containing a confidentiality code (some profiles require at least one). Multiple values of confidentialityCode are coded by specifying multiple classification objects.

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	**HL7 Privacy and Security Healthcare Classification System [HCS]**	**Final (Normative)**	**Production**	●●●●○	Yes since required in DS4P and optional in XD*	**Free**	**N/A**

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Feedback requested	• ITI-3 p. 63 Use of Sensitivity tags expose the nature of the sensitivity and should be used only when the end-to-end confidentiality of the tags can be assured.

- o HL7 and its Security and Community Based Collaborative Care (CBCC) Work Groups recommend that the ISA include the normative HL7 Role Based Access Control Catalog for purposes of enabling trading partners to exchange interoperable role information in patient consent directives and trust policies, and to enable access control systems to enforce data segmentation. This standard is based on ASTM E 1986 roles and maps these to well understood healthcare information objects to create coded RBAC permissions, which can be shared with trading partners that require recipients to comply with the sender's access control policies.
  This approach is used in the Authorization Framework used for Exchange where roles of recipients are matched to determine permission of the resources requested/disclose.

Interoperability Need: Representing role based access control

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	**HL7 Role Based Access Control Catalog**	**Final**	**Production**	●●●●○	to the extent used in MU Exchange	**Free**	**N/A**

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Near term enhancement: HL7 Security and CBCC WGs are balloting an update to the RBAC Catalog to include Attribute Based Access Control codes for clearances, which leverage the HL7 Healthcare Classification System security labels, to enable data segmentation.	• Conveyance of role and clearances in attribute and authorization certificates must be encrypted.

- We propose to add the SAMHSA National Sensitive Code Value set from VSAC, which is comprised of standard codes and which will likely continue to grow with input from Veterans Health Administration and other authors who have a privacy or consent policy basis for including additional codes. The intent is to curate a national sensitive code list, which may have international applicability, to enable policy makers, standards developers, and implementers to select relevant codes representing sensitive conditions, medications, orders, billing, demographic, and other codes indicative of specially protected health information governed under organizational, jurisdictional, or healthcare consumer privacy policies, and which may be more additionally governed by healthcare consumer consent directive. For example, substance use disorder treatment under 42 CFR Part 2 and sickle cell anemia under Title 38 Section 7332 for which healthcare consumers receiving care under these programs may consent to disclose.

Interoperability Need: **Representing sensitive condition, medication, orders codes indicative of specially protected health information**

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	**National Sensitive Code Value Set**	**Final**	**Pilot**	●○○○○	No	**Free**	**N/A**

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• A number of HL7 Standards, including the HL7 Data Segmentation for Privacy, HL7 Consent Directive CDA IG, HL7 Data Provenance IG, HL7 Privacy and Security Classification System, HL7 PASS Access Control and Security Label Service Functional Models; HL7 Version 2 Message Header [MSH-8 in particular], Admit, Discharge, and Transmit Access Restriction Value [ADT ARV], Consent Message [MDM with CON segment], Confidentiality element used in some Version 2 Messages, or optional CON segment for use in any Version 2 Messages Types; and FHIR Security Labels, FHIR Consent, and FHIR Consent Directive all depend on determining whether focal content includes standard sensitive codes governed under applicable privacy or consent policies for assignment of HL7 Security Labels and Access Control. The ability to reference the SAMHSA VSAC National Sensitive Code value set would enhance these standards' ability to specifically reference an	• Any security pattern for trust, provenance, authorization, access control, including data segmentation, security labeling, and privacy protective services. Any standard for capturing or conveying legally binding healthcare consumer consent directives, and any derivation of consent content used for consent directive management.

interoperable set of curated sensitive codes rather than leaving it up to implementers to determine which sensitive codes comprehensive represent specially protected information under various privacy and consent policies.	
• The ability of the standards listed above to leverage a national value set of sensitive codes is limited only by the additions to that value set to date. As more codes are added, this limitation will dissipate.	
• The sensitive code systems in the VSAC value set are in production since they are code standards for Meaningful Use including SNOMED, RxNorm, LOINC, ICD-9 and ICD-10. Adoption of the VSAC sensitive code value set is in the early stages as the community is just now becoming aware that they can use it. In addition, the value set does not yet include all known sensitive codes, e.g., sickle cell anemia, which is considered sensitive under Title 38 Section 7332. However, we anticipate additional known sensitive codes being added as authors are tasked to do so.	

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Section II: Content/Structure Standards and Implementation Specifications
- II-A: Admission, Discharge, and Transfer
    - o Interoperability Need: Sending a Notification of a Patient's Admission, Discharge and/or Transfer Status to Other Providers
        - ▪ We recognize that HL7 ADT messages are mostly used within provider/healthcare organizations to inform departmental systems on ADT activities, but they are used across provider/healthcare organizations at times as well to notify other providers of a patient's status. However, X12 278 is used for notifications across/inter-provider, including to patient's care team, as well so it seems this should be mentioned, unless the use case would preclude that. We suggest to clarify the use case with a paragraph to provide context and then document either one, the other, or both. If only one is intended for this use case, we suggest to add another use case to cover the use of the other standard.
    - o Interoperability Need: Sending a Notification of a Patient's Admission, Discharge and/or Transfer Status to the Servicing Pharmacy
        - ▪ No comment

- II-B: Care Plan
    - o Interoperability Need: Documenting Patient Care Plans
        - ▪ We suggest that ONC clarify the use case through a paragraph that this interoperability need is limited to exchanging a snapshot of a care plan, but does not cover the dynamic maintenance of a joint, cross-provider care team care plan. The standard referenced is not suitable to that purpose, but is well suited to just exchange for informational purposes a most current care plan.
    - o Interoperability Need: Documenting, Planning and Summarizing Care Plans for Patients with Cancer
        - ▪ No comment

- II-C: Clinical Decision Support
    - o Interoperability Need: Shareable Clinical Decision Support
        - ▪ We note that "HL7 FHIR Profile: Quality" will be made fully compatible with the HL7 Data Access Framework (DAF) FHIR profile per ballot reconciliation at the September 2016 HL7 Work Group Meeting. Also note that this set of profiles will be extended to incorporate more detailed clinical models through the HL7 Clinical Information Modeling Initiative (CIMI).
        - ▪ HL7 Implementation Guide: Clinical Decision Support Knowledge Artifact Implementation Guide, Release 1.3, Draft Standard for Trial Use. Adoption level should be 2. The Veterans Administration is using this specification as part of their ongoing work to implement order sets.
        - ▪ HL7 FHIR Implementation Guide: Clinical Quality Framework (CQF on FHIR). This specification is now simply the Clinical Reasoning Module of FHIR. Note that this module is expected to supersede many of the existing specifications once sufficiently mature.
    - o Interoperability Need: Provide Access to Appropriate Use Criteria

- HL7 FHIR Implementation Guide: Clinical Quality Framework (CQF on FHIR). This specification is now simply the Clinical Reasoning Module of FHIR. Note that this module is expected to supersede many of the existing specifications once sufficiently mature.
  - Interoperability Need: Communicate Appropriate Use Criteria with the Order and Charge to the Filling Provider and Billing System for Inclusion on Claims.
    - No comment

- II- D: Clinical Quality Measurement
  - Interoperability Need: Sharing Quality Measure Artifacts for Quality Reporting Initiatives
    - HQMF: We agree with naming it here; Implementation Maturity should be "Production" (not Pilot); Adoption level is correct; other elements are correct; Roadmap note to be included in the Limitations, Dependencies, Preconditions box: HQMF is expected to go to normative in 2017; While HQMF will still be in use, we expect that systems may eventually transitioned it to FHIR Clinical Reasoning
    - FHIR Profile: Quality: We agree with naming it here and current content; however we are requesting that this particular document be renamed from "FHIR Profile: Quality" to "FHIR Profile: Quality (QI-Core)". Also, the URL link takes people to the STU Comment site. The URL should be corrected to take people to the QI-Core site.
    - CQL: agree with naming it here and current content; The URL takes people to the STU Comment site. It should be corrected and take people to the CQL document (not the STU comment site).
    - QDM-based HQMF: Agree with naming it here; The name should be modified to "Release 1.4 DSTU 4 (based on HQMF 2.1)"; Implementation maturity and Adoption level are correct; Federally required should be changed to "yes" since this is required by a federal program (Medicare) and the definition of this column includes "…adopted in regulations, referenced as a federal program requirement, or referenced in a federal procurement…."; Also, the URL takes people to the wrong site. It should be corrected and take people to the QDM-Based HQMF document.
    - Emerging – CQL-based HQMF: agree with naming it here; name should be "Release 1 DSTU 1" and with content; Also, the URL is taking people to the HL7 Standards Master Grid, and not to the CQL-based HQMF document. URL should be corrected. Roadmap note to be included in the Limitations, Dependencies, Preconditions box: CQL-baser HQMF major release 2 expected in 2017
    - Emerging – CQF on FHIR: agree with naming it here and with content; Roadmap note to be included in the Limitations, Dependencies, Preconditions box: The CQF on FHIR will be transitioned to FHIR Clinical Reasoning
    - Addition: We recommend adding FluentPath as an emerging standard, in development, pilot status, one-dot adoption, not required, free of charge, no test. On this point, we recommend adjusting the name (FluentPath) to the most appropriate name for this emerging standard, when such name is

finalized by HL7.

- II-E: Clinical Quality Reporting
    - o Interoperability Need: Reporting Aggregate Quality Data to Federal Quality Reporting Initiatives
        - CDA: We agree with naming it here and with content
        - QRDA Cat III: We agree with naming it here; the ballot reference name should be corrected to "HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture – Category III (QRDA III) Release 1 DSTU Release 1"
        - Emerging - QRDA Cat III: We agree with naming it here and with content; name should be changed to "DSTU Release 3" rather than "DSTU Release 2"; also, Federally required should be changed to No (can't mandate something that is in development…); finally, since we are completing this ballot cycle the resolution of comments, and expect to publish a new version – which we expect it will be called "QRDA III Release 1.1" – perhaps ONC should consider calling it that way
    - o Interoperability Need: Reporting Patient-level Quality Data to Federal Quality Reporting Initiatives
        - CDA: We agree with naming it here and with content
        - QRDA Cat I: We agree with naming it here; the name should be "Release 1 DSTU 3"; other content correct
        - Emerging - QRDA Cat I: We agree with naming it here; the name should be "Release 1 DSTU 4" (right now the name is identical to the one listed above); the URL should be corrected to go to the HL7 site for DSTU Release 4 (not 3, as it is currently set to go to); other content correct

- II-F: Data Provenance
    - o Interoperability Need: Establishing the Authenticity, Reliability, and Trustworthiness of Content Between Trading Partners.
        - HL7 considers the HL7 CDA Data Provenance DSTU to be a compilation of patterns for capturing and conveying data provenance that have been used throughout its product families in many specifications such as the TXA segment used in HL7 v2, v3, CDA, and FHIR to record transcription, document and order lifecycle, and legal authentication; and the various approaches to tracking status changes of e.g., orders, referrals, scheduling, and financial transactions. As health information exchange increases the number of health record copies, which may flow through many end points, and may be altered legitimately, erroneously, or purposefully along the way, that it is crucial for patient safety, privacy, security, and trust as well as the integrity of the legal record that ONC consider promoting this standard at greater speed beyond what it is already doing by supporting the Data Provenance Pilots.

- II-G: Drug Formulary & Benefits
    - o Interoperability Need: The Ability for Pharmacy Benefit Payers to Communicate Formulary and Benefit Information to Prescribers Systems
        - No comment

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- II-H: Electronic Prescribing
  - Interoperability Need: A Prescriber's Ability to Create a New Prescription to Electronically Send to a Pharmacy
    - We suggest adding a provision that when using a mobile device connected to an EHR these standards apply as the EHR generates the transactions. It is not clear, and NCPDP may have further information, when a mobile device is used for e-prescribing whether the same or different standards are used.
  - Interoperability Need: A Prescriber's Ability to Grant a Refill Request to the Pharmacy
    - No comment
  - Interoperability Need: Allows the Pharmacy to Respond to Prescriber with a Change on a New Prescription
    - No comment
  - Interoperability Need: Cancellation of a Prescription
    - No comment
  - Interoperability Need: Pharmacy Notifies Prescriber of Prescription Fill Status
    - No comment
  - Interoperability Need: A Prescriber's Ability to Obtain a Patient's Medication History
    - No comment
  - Interoperability Need: Allows Prescriber to Respond to a Prior Authorization for a Medication Electronically to the Payer/Processor.
    - No comment
  - Interoperability Need: Prior Authorization Cancel Request
    - No comment

- II-I: Family health history (clinical genomics)
  - Interoperability Need: Representing Family Health History for Clinical Genomics
    - No comment
  - Interoperability Need: Representing Patient Family Health History Observations
    - No comment

- II-J: Images
  - Interoperability Need: Medical Image Formats for Data Exchange and Distribution
    - No comment
  - Interoperability Need: Format of Medical Imaging Reports for Exchange and Distribution
    - No comment
  - Interoperability Need: Format of Radiology Reports for Exchange and Distribution
    - No comment

- II-K: Laboratory

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- o Interoperability Need: Receive Electronic Laboratory Test Results
    - It is unclear why LRI R1 dropped to one bullet for Adoption Level considering 2014 Edition still includes a criterion for it, while OPPS will drive it further with need for structured data support. This is an example where the difference between HIT being capable of using it vs. provides and laboratories actually using it.
    - While LRI may not be widely used, HL7 V2 is used widely for this purpose. Within V2, most implementations are local interpretations (i.e., not nationally adopted interpretations) of V2.3.1 through V2.5.1. Although we support the focus on implementation guides, having insight into the adoption level of the base standard when implementation guides have not been widely adopted is helpful to understand. However, it should then be noted that implementers are strongly encouraged not to use the base standard, rather pursue the implementation guide(s) referenced.
    - We strongly urge inclusion of the HL7 Lab EHR-S IG which clarifies sender/receiver responsibilities to achieve end-to-end interoperability.
    - We note that work is in progress to include security/consent considerations into these guides that are anticipated to be part of the January 2017 ballot cycle.
- o Interoperability Need: Ordering Labs for a Patient
    - We note that work is in progress to determine how security/consent considerations into this guide that are anticipated to be part of the January 2017 ballot cycle.
- o Interoperability Need: Support the Transmission of a Laboratory's Directory of Services to Health IT.
    - No comment.

- II-L: Medical Device Communication to Other Information Systems/Technologies
    - o Interoperability Need: Transmitting Patient Vital Signs from Medical Devices to Other Information Systems/Technologies
        - We suggest changing Adoption Level from two to three (shaded circles). Rationale: the IHE-PCD Integration Profiles have been successfully tested and incorporated by twenty-eight medical device companies and forty-five products (as of August 2015, Commercially Available IHE-PCD Systems).
        - "Test Tool Availability" column: Replace "N/A" with "Yes". Rationale: NIST has publically available HL7 Version 2 test tools which test compliance to seven IHE-PCD Integration Profiles (http://wiki.ihe.net/index.php/PCD_Profiles). The online, web-based, freely available conformance tooling (http://ihe-pcd-precon.nist.gov/ and http://ihe-pcd-con.nist.gov/) have been available and used over the 10 years of IHE-PCD test events (known as the "Pre-Connectathon" and "Connectathon").
        - Additionally, NIST has available the "Rosetta Terminology Mapping Management System" [RTMMS] (rtmms.nist.gov) web-based, freely available (via a Royalty Free Agreement with IEEE Standards Association) nomenclature data source compliant to the ISO/IEEE 11073-10101 (Nomenclature standard). The RTMMS provides ISO/IEEE 11073 harmonized terminology which includes terminology reference identifiers,

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codes, descriptions, systematic names, and common terminology (used in medical practice) used for semantic content validation.
- We are actively incorporating HL7 FHIR support in the IHE-PCD specifications as part of the joint HL7 / PCHA-Continua / IHE Devices on FHIR project, with IHE testing targeting 2017 January.

- II-M: Patient Education Materials
    - Interoperability Need: A Standard Mechanism for Clinical Information Systems to Request Context-Specific Clinical Knowledge Form Online Resources
        - No comment

- II-N: Patient Preference/Consent
    - Interoperability Need: Recording Patient Preferences for Electronic Consent to Access and/or Share their Health Information with Other Care Providers
        - We suggest that the security patterns below that were removed compared to the 2016 ISA are re-introduced as they remain applicable, and applied to other transactions. If considered generally applicable, they could perhaps be documented once in an overall Applicable Security Patterns for Consideration section.
            - Secure Communication – create a secure channel for client-to-serve and server-to-server communication.
            - Secure Message Router – securely route and enforce policy on inbound and outbound messages without interruption of delivery.
            - Authentication Enforcer – centralized authentication processes.
            - Authorization Enforcer – specified policies access control.
            - Credential Tokenizer – encapsulate credentials as a security token for reuse (examples – SAML, Kerberos).
            - Assertion Builder – define processing logic for identity, authorization and attribute statements.

- II-O: Public Health Reporting
    - Interoperability Need: Reporting Antimicrobial Use and Resistance Information to Public Health Agencies
        - No comment
    - Interoperability Need: Reporting Cancer Cases to Public Health Agencies
        - We should note that SDC defines the framework and structure to establish and collect questionnaires/answers. However, it does not contain the library of actual questionnaires and vocabulary for specific use cases. We suggest that this is clarified to avoid everybody having to support every questionnaire/answer template. Rather this should be refined over time to identify specific questionnaire/answer sets for specific use cases.
        - Note that work is in progress to include NAACCR requirements/feedback into LRI to accommodate cancer related pathology reporting. Targeted for January 2017 Ballot.
    - Interoperability Need: Case Reporting to Public Health Agencies
        - We appreciate the inclusion of the emerging FHIR standard. However, in the absence of implementation guides and profiles specific to this use case,

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implementations may become very diverse, akin to what happened to HL7 V2, V3, and CDA. We suggest that the reader is made more clearly aware of this challenge and are asked to contribute to efforts to develop the necessary implementation guides so we can arrive at consistent data exchange for the same use case.

- o Interoperability Need: Electronic Transmission of Reportable Lab Results to Public Health Agencies
  - We note that the ELR implementation guide will be fully integrated with the LRI guide to ensure consistency where necessary across ambulatory and public health reporting, while allowing for necessary variations. This work is expected to go into ballot in January 2017.
- o Interoperability Need: Sending Health Care Survey Information to Public Health Agencies
  - The HL7 CDA R2 Implementation Guide (IG): National Health Care Surveys Release 1.0 is currently referenced in Section II-O: Public Health Reporting for Sending Health Care Survey Information to Public Health Agencies. The draft 2017 ISA indicates that test tools are not available for this IG. However, conformance test tooling developed by the National Institute of Standards and Technology in collaboration with the Centers for Disease Control and Prevention/National Center for Health Statistics is available for Release 1.0 and Release 1.1 at http://cda-validation.nist.gov/cda-validation/muNHCS.html.
  - The HL7 CDA R2 Implementation Guide (IG): National Health Care Surveys Release 1.0 DSTU has evolved into two improved DSTU Releases: 1.1 to support national surveys for inpatient data collection and 1.2 in response to vendors' comments on the earlier release. We recommend that the 2017 ISA reference all three releases of this standard since Rel. 1.0 has been identified for Meaningful Use Stage 3 certification and the National Center for Health Statistics recommends sending either Rel. 1.1 or Rel. 1.2 (preferred) to fulfill the complete set of survey requirements.
- o Interoperability Need: Reporting Administered Immunizations to Immunization Registry
  - No comment
- o Interoperability Need: Reporting Syndromic Surveillance to Public Health (Emergency Department, Inpatient, and Urgent Care Settings)
  - No comment

- II-P: Representing clinical health information as a "resource"
  - o Interoperability Need: Representing Clinical Health Information as "Resource"
    - We clearly support the adoption of FHIR as it will be able to support a variety of emerging use cases enabling data access for e.g., viewing, or decision support, at a more granular data element level. While both V2 and V3 are capable of representing data at more granular levels than messages or documents, doing so in support of RESTful and other services as well as supporting more lightweight, mobile applications is more complicated if not impractical. This is further recognized by the substantial support from the industry to develop and adopt FHIR, e.g.,

Argonaut. The level of granularity afforded by FHIR resources that can be accessed individually or pulled together for a service, message, or document is very powerful. However, in the context of the ISA use cases it is unclear why a use case is defined as "Representing clinical health information as a "resource"". Using "resources" is a means to an end, not an end in and of itself. A real use case should focus on the end defining a real end user need, e.g., query more granular data. We therefore suggest not including the use case as described here, but rather focus on the actual use cases. This is effectively already done in Section III. I.e., the term "resource" should not be part of the use case description, rather part of the standard that happens to express the relevant health information as FHIR resources.

As such use cases are defined and FHIR is considered a viable standard to support those use cases we must note the following considerations, also stated elsewhere:

- The need for profiles to enable FHIR to (1) fully represent the semantics of many interoperability scenarios given FHIR resources' focus on the 80/20 rule and (2) define restrictions that enable semantic interoperability, e.g., for value set bindings. Without such profiles and implementation guides we will experience the same widely disparate use of the base V2, V3 / CDA standards where implementation guides were not available.
- The need of underlying clinical data models such as could be provided by the Clinical Information Modeling Initiative (CIMI) for clearly establishing detailed semantics using FHIR and the inter-relationship among these detailed clinical models

- II-Q: Research
  - Interoperability Need: Submission of Analytic Data to FDA for Research Purposes
    - No comment
  - Interoperability Need: Pre-population of Research Forms from Electronic Health Records
    - No comment
  - Interoperability Need: Integrate Healthcare and Clinical Research by Leveraging EHRs and other Health IT Systems while Preserving FDA's Requirements
    - No comment
  - Interoperability Need: Complete Disease Registry Forms and Submit to Reporting Authority (ACC)
    - No comment
  - Interoperability Need: Registering a Clinical Trial
    - Since the intent of the ISA is to list available standards, not necessarily best available, we suggest to recognize that HL7 V2.x supports messages and linkages to set up a clinical trial and associate data (e.g., orders, results, administrations) to a clinical trial

- II-R: Segmentation of sensitive information

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- o Interoperability Need: Document-Level Segmentation of Sensitive Information
  - ▪ We suggest that the Advisory increase the maturity measures for the normative Consolidated HL7 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1 to:
    - • Implementation Maturity = Production at header and XD
    - • Adoption Level = 61% to 80% adoption
    - • Regulated = yes, as it is named in the 2015 Edition Health IT Certification Criterion at § 170.315(b)(7) and § 170.315(b)(8)

The rationale for the higher adoption level is that for C-CDA transmission, document level DS4P is required in the C-CDA General Header. We would agree that data segmentation at the section level is still very much at the early pilot stage, but the Interoperability Need does indicate "document-level". To avoid confusion when indicating a higher adoption level is to include in the Limitations, Dependencies, etc., a clear statement that this is only at the C-CDA General Header level and NOT at the section level.

We do note that this standard should actually be listed in combination with the relevant exchange use case as this standard is not used on its own. Specifically it should be listed with use cases using C-CDA.

  - ▪ Add to Limitations
    - • Suite of conformance tests developed by ONC DS4P project
  - ▪ Add to Applicable Security Patterns for Consideration:
    - • Access Control systems must ensure that only authorized users are able to access the DS4P Privacy Marking section or any Privacy Annotations that include HCS

- • II-S: Summary care record
  - o Interoperability Need: Support a Transition of Care or Referral to Another Health Care Provider
    - ▪ We suggest to include the emerging Companion Guide for C-CDA R2.1 which has gone through ballot, is going through ballot reconciliation and is being prepared for publication.

- • Suggested Use Cases to Add
  - o We note that inclusion of data segmentation for privacy in the 2015 Edition Health IT Certification Criterion it is incumbent on outbound (send) implementers to be capable of manually or computably transforming patient preferences into security labeling on the outbound CDAs. It is also incumbent on inbound (receive) implementers to parse these preferences into enforceable access control decisions. If the inbound implementer receives unstructured consent directives or references to external location of patient agreed to BPPC consent directive templates, then these implementers have an additional step to discovery, retrieve, and manually parse these unstructured patient preferences. This does not scale. While we appreciate the inclusion of the DS4P Implementation Guide, we suggest including the HL7 Consent Directive CDA IG as it provides the only available means to consistently and automatically generate and consume patient directives in CDA.

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The HL7 Privacy Consent Directive CDA IG enables interoperable and computable consents expressed as structured HL7 privacy and security vocabulary, BPPC, and as XACML policies. This standard is the only specification available for encoding consent rules that can be enforced by data segmentation. The BPPC alone cannot meet these criteria, bus is also able to be encapsulated in the Consent Directive CDA IG as unstructured content, as a Consent URI, as an XACML rule, or as an externally reference document. The HL7 Consent Directive CDA IG enables an interoperable "glide path", as coined by John Halamka, for trading partners at various levels of maturity to support patient preferences as end user develop capabilities to consume and computably enforce these consent directives.

Interoperability Need: Consent Directives

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	**HL7 Implementation Guide for CDA®, Release 2: Consent Directives, Release**	**Final Note** in process of being published as **Normative**	**Production**	●○○○○ *Implemented in Prince George's County and in other SAMHSA Consent2Share Operational installations.*	No	**Free**	**Yes, SAMHSA Consent2Share has conformance testing tools**

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Feedback requested	• As with any transaction related to contracts, policies, consent directives, access control mechanisms need to be in place to enforce sender's security, privacy, and trust policies.

o We recommend that the ISA include the HL7 Data Provenance CDA IG Draft Standard for Trial Use at the pilot and lowest adoption level as this is the only available specification that constrains the CDA, C-CDA, and DS4P to ensure that trading partners can establish Provenance policies as to the key metadata needed to establish the authenticity, reliability, and trustworthiness of the CDA content they exchange. HL7 views this as a current and steadily increasing business need as healthcare "consumer" systems deal with the proliferation of copies, extracts, and aggregation of CDA content the WGs anticipate them receiving, and these systems' need to develop automated "integration" rules such that, e.g., trusted content can be automatically integrated while less reliable content can be

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It is also important to note that Data Provenance is very important for mobile health, e.g., for data that flows from mobile devices into EHRs and PHRs. It will be critical to capture where the data came from (e.g., the user, device, and the app) and to understand the data quality. Even the specific level of the software that produced the data may need to be tracked. CDA DPROV may# not be the appropriate standard for mobile health if CDA is not the container by which the data is exchanged. There are other standards, such as FHIR Provenance resource, that need to be evaluated. HL7's Mobile Health WG is currently developing a framework for consumer apps that includes "Data authenticity, Provenance, and Associated Metadata" in its requirements.

Interoperability Need: Data Provenance

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	**HL7 Data Provenance CDA IG Draft Standard for Trial Use (official link is challenged, this link can be used internally while we get the right link)**	**Final DSTU**	**Pilots – ONC DPROV**	●○○○○	no	**Free**	**N/A**

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Feedback requested	• Application of the DPROV IG constraints may enforce inclusion of sensitive information such as the provide type, id, and role, which may disclose protected information. In addition, since the DPROV IG inherits both the C-CDA General Header and the DS4P CDA constraints, the same precautions recommended for DS4P and XD* regarding protected security labels pertains.

    o In response to the statement "We received requests to include standards related to transfer on pregnancy, birth information, newborn nursery, newborn screening, and related topics. ONC will continue to explore inclusion of these standards for future ISA updates. " in Appendix 3 we suggest to add the following interoperability need and associated standards:

        § Vital Statistics Reporting

- birth & fetal death reporting (v2.5.1 and CDA),
- death reporting (v2.6 and CDA),
- birth defects (CDA), CCHD (v2.6) and EDHI (v2.6)

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Section III: Standards and Implementation Specifications for Services
- III-A: "Push" Exchange
  - Interoperability Need: An Unsolicited "Push" of Clinical Health Information to a Known Destination Between Individuals and Systems
    - We suggest adding the following to the Applicable Security Patterns for Consideration:
      - Patient Consent Information - Identifies the patient consent information that:
        - May be required to authorize any exchange of patient information
        - May be required to authorized access and use of patient information
        - May be required to be sent along with disclosed patient information to advise the receiver about policies to which end users must comply
      - Security Labeling – the health information is labeled with security metadata necessary for access control by the end user.
    - The Adoption Level for Direct raises a question whether this reflects the adoption by software developers to have it available, or the actual use. If the intent is to indicate adoption by software developers we would agree with this assertion, but if it is to reflect actual use we understand this to be lower. This variance should be clarified.
    - We suggest that where a specification is not (yet) formally owned by an SDO to maintain such specification that it is highlighted. Specifically, we understand that Direct is not yet formally owned by a particular organization to ensure ongoing maintenance and updates. This should not disqualify the specification from inclusion, but does contribute to the transparency considering the risks around sustainability, governance, and other maintenance and updates.
  - Interoperability Need: An Unsolicited "Push" of Clinical Health Information to a Known Destination Between Systems
    - No comment
  - Interoperability Need: Push Communication of Vital Signs from Medical Devices
    - "Implementation Maturity" column: Replace 'Pilot' with 'Implementation' as there are products in commercial distribution. Also technologies for communicating vital signs from medical devices based on 11073 are in production - as well as active development for additional technologies, including SOA / web services architectures and HL7 FHIR specifications.
    - We suggest changing Adoption Level from one to two (shaded circles). Rationale: the ISO/IEEE 11073 Medical Data Communication family of medical standards is the basis for the Integrating the Healthcare Enterprise Patient Care Device (IHE-PCD) Integration Profiles which have been successfully tested and incorporated by twenty-eight medical device companies and forty-five products (as of August 2015, Commercially Available IHE-PCD Systems). The Personal Connected Health Alliance

(PCHA) (www.continuaalliance.org/pchalliance) maintains lists of approved products which also collect vital sign information.

- ▪ "Test Tool Availability" column: Replace "No" with "Yes".
  Rationale: NIST has a 11073-10101 (Nomenclature) publically available tool. The online, web-based, freely available (via a Royalty Free Agreement with IEEE Standards Association) nomenclature data source known as the "Rosetta Terminology Mapping Management System" (rtmms.nist.gov) provides ISO/IEEE 11073 harmonized terminology which includes terminology reference identifiers, codes, descriptions, systematic names, and common terminology (used in medical practice). Additionally, the Personal Connected Health Alliance (PCHA) (www.continuaalliance.org/pchalliance) has ISO/IEEE 11073 tools for testing certification to the published Continua Design Guidelines (http://www.continuaalliance.org/products/design-guidelines).
  - ▪ Under the "Limitations, Dependencies, and Preconditions for Consideration:" section add an additional bullet
    - • "ISO/IEEE 11073 suite of standards for various medical devices" is included in the FDA's "Recognized Consensus Standards Database" (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm).
  - ▪ Under the column entitled "Limitations, Dependencies, and Preconditions for Consideration:" replace the word "suite" with "family" in the text "ISO/IEEE 11073 is a suite of standards for various medical devices" to conform with the IEEE preferred designation.

- • III-B: Clinical Decision Support Services
  - o Interoperability Need: Providing Patient-Specific Assessments and Recommendations Based on Patient Data for Clinical Decision support
    - ▪ QuICK should be QUICK, ad with a space after "Draft".
    - ▪ We note that the Clinical Reasoning Module of FHIR is expected to supersede many of the existing specifications once sufficiently mature.
  - o Interoperability Need: Retrieval of Contextually Relevant, Patient-Specific Knowledge Resources from Within Clinical Information Systems to Answer Clinical Questions Raised by Patients in the Course of Care
    - ▪ Adoption Level of the first specification should be 4. It is required to support the implementation guides which are at 4.

- • III-C: Image Exchange
  - o Interoperability Need: Exchanging Imaging Documents Within a Specific Health Information Exchange Domain
    - ▪ No comment
  - o Interoperability Need: Exchanging Imaging Documents Outside a Specific Health Information Exchange Domain
    - ▪ No comment

- • III-D: Healthcare Directory, Provider Directory

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- o Interoperability Need: Listing of Providers for Access by Potential Exchange Partners
    - ▪ No comment

- • III-E: Public Health Exchange
  - o Interoperability Need: Query/Response for Immunization Reporting and Exchange
    - ▪ No comment

- • III-F: Publish and Subscribe
  - o Interoperability Need: Publish and Subscribe Message Exchange
    - ▪ No comment

- • III-G: Query
  - o Interoperability Need: Query for Documents Within a Specific Health Information Exchange Domain
    - ▪ No comment
  - o Interoperability Need: Query for Documents Outside a Specific Health Information Exchange Domain
    - ▪ No comment
  - o Interoperability Need: Data Element Based Query for Clinical Health Information
    - ▪ No comment

- • III-H: Resource Location
  - o Interoperability Need: Resource Location Within the US
    - ▪ No comment

- • Additional Use Case Suggestions
  - o We recommend that the ISA include the HL7 PASS Access Control Service Functional Model, which passed the October 2015 normative ballot after a 2 year DSTU period and is now undergoing ballot reconciliation and expected to pass. This standard specifies the access control functionalities required for interoperable exchange of health information including conveyance of Obligations to which end users much comply, e.g., to support data segmentation. Our recommendations are captured in the proposed table below.

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard		Final	Pilot	●○○○○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:

• Feedback requested	• Feedback requested

o We recommend that the Advisory include the normative HL7 PASS Security Labeling Service Functional Model, which specifies the technology agnostic services required to implement an Access Control System capable of segmenting health information both for access and use by users within the trust domain and for disclosure to end users outside of a trust domain. HL7 considers SLS to be widely adopted because it describes current Access Control processes that have a long history of use. Currently many Access Control Systems apply Confidentiality and Purpose of Use security labels in XD* metadata for Exchange and Direct XDR/XDM or as values for the Confidentiality attributes on all CDA Headers and Sections. Where Confidentiality or Purpose of Use security labels are used to enforce the policies represented by these labels, especially jurisdictional laws such as 42 CFR Part 2, HITECH Self-pay, and Title 38 Section 7332 or state laws more stringent than HIPAA.

Our recommendations are captured in the proposed table below.

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	HL7 PASS Security Labeling Service Functional Model	Final	Production	●○○○○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Feedback requested	• Feedback requested

Section IV: Questions and Requests for Stakeholder Feedback

As with the previous Interoperability Standards Advisories (ISA), posing questions has served as a valuable way to prompt continued dialogue with stakeholders to improve the ISA. Your feedback on the questions posed below is critical and we encourage answers to be submitted as part of the current public comment process.

General

1. For each standard and implementation specification there are six assessment characteristics, for which detailed information has been received and integrated. However, some gaps remain. Please help complete information that is missing or noted "feedback requested . Additionally, assessing the adoption and maturity of standards is an ongoing process, so please continue to provide feedback if you believe something has changed or is not correct. Answer: See feedback above.

2. The table beneath the standards and implementation specifications includes limitations, dependencies, and preconditions. Given the enhancements made, please comment on accuracy and completeness and where information gaps remain, forward applicable content. Answer: See feedback above.

3. For the Implementation Maturity characteristic for the standards and implementation specifications, ONC plans to publish a link, where available, to published maturity assessments based on known published criteria. Please help identify any publications that are publically available and provide the hypertext links to those resources. Answer: See feedback above.

4. For the Adoption Level characteristic for the standards and implementation specifications, ONC plans to publish reference annotations or links to publicly available documentation known about adoption levels for listed standards.   Please help identify any publications that are publicly available and provide the hypertext links to those resources. Answer: We appreciate any documentation and references that underpin the Adoption Level assertions.

5. For the Test Tool Availability characteristic for the standards and implementation specifications, ONC plans to publish references, where available, a to the publicly available test tool. Please help identify any publicly available test tools. Answer: See feedback above.

Section I: Vocabulary/Code Set

6. Within the Section I tables, Value Sets have been selected to substitute for what otherwise references Security Patterns in Sections II and III. Please review and provide feedback on placement, accuracy and the completeness of the selected value sets. Answer: We suggested various places where Security Patterns should be applied.

7. For subsection I-D: Functional Status/Disability, the Health Information Technology Standards Committee recommends using SNOMED®/LOINC® observation paring for this interoperability need. Do you support this approach?
   Answer: We support this approach.

8. For subsection I-H: Industry and Occupation, there continues to be varied opinion on the standards or implementation specifications to be sited in these areas. Please review and provide feedback on what should be included and/or whether these areas should be removed.
   Answer: No comment

9. For subsection I-R: Sexual Orientation and Gender Identity, Interoperability Need: Representing patient sex (at birth), what are the appropriate genetic identifiers or gender determinants (e.g., gonadal sex, karyotype sex) for potential inclusion in the ISA.
   Answer: No comment

10. For subsection I-S: Social Determinants please help identify the adoption level of LOINC® for each of the Interoperability Needs.
    Answer: No comment

11. Are there additional psychosocial Interoperability Needs with corresponding standards that should be included in the ISA?
    Answer: No comment

12. For subsection I-T: Tobacco Use (Smoking Status), because of the current limitations, what surveys, instruments or tools are being used to collect tobacco use information that is more complete that the current coding methodologies?
    Answer: No comment

Section II: Content / Structure

13. For the existing interoperability need, "representing clinical health information as a resource", public comments expressed this may not be the best language to describe this area. Please provide feedback on whether or not this is correct or recommend alternative language that better describes this interoperability need.
    Answer: See feedback above

14. Opinions vary in the way (messaging vs. transport) the ISA should represent FHIR. Please review and provide feedback on the manner FHIR should be represented.
    Answer: We suggest to clearly distinguish whether FHIR is referenced for its content or its transport (and if so, which transport) to avoid confusion considering FHIR can be used in a services, RESTful, document, and/or messaging environment.

Appendix I: Sources of Security Standards

15. Are there other authoritative sources for Security Standards that should be included in Appendix I?
    - HL7 CDA® R2 Implementation Guide: Patient-Friendly Language for Consumer User Interfaces, Release 1

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Category: Privacy and Consent
Description: Provides a plain language healthcare vocabulary for patient comprehension. This vocabulary is targeted specifically toward healthcare consumer user interfaces which create outputs for consumer consumption such as consent directives, reports of disclosures, and notices of privacy practices. IG provides a mapping of technical/legal security and privacy jargon to plain language vocabulary, which increases the likelihood that patients understand the choices they make while ensuring their choices are correctly translated across the system.
Link: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=412

- HL7 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1
Category: Privacy and Consent
Description: Creates constraints to standards for Meaningful Use consistent with federal and state privacy policies. Enables the exchange of protected/sensitive personal health information. Supports secure exchange of health information and privacy annotations applied to documents, messages, or atomic data elements.
Link: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=354

- HL7 Healthcare Privacy and Security Classification System (HCS), Release 1
Category: Privacy and Consent
Description: The HCS enables interoperable exchange of security metadata by access control systems via automated labeling and segmentation of protected health information to ensure that only authorized users access this information.
Link: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=345

- HL7 Version 3 Standard: Privacy, Access and Security Services; Security Labeling Service, Release 1 (SLS)
Category: Privacy and Consent
Description: Specifies the technology agnostic services required to implement an Access Control System capable of segmenting health information both for access and use by users within the trust domain and for disclosure to end users outside of a trust domain.

- HL7 Implementation Guide for CDA®, Release 2: Consent Directives, Release 1
Category: Privacy and Consent
Description: Enables interoperable and computable consents expressed as structured HL7 privacy and security vocabulary, BPPC, and XACML policies. This standard is the only specification available for encoding consent rules that can be enforced by data segmentation. It enables an interoperable "glide path," as coined by John Halamka, for trading partners at various levels of maturity to support patient preferences as end user develop capabilities to consume and computably enforce consent directives. The only available means for automating the generation and consumption of patient consent directives in CDA based exchanges is to use the HL7 Consent Directive CDA IG.
Link: HL7 Implementation Guide for CDA®, Release 2: Consent Directives, Release 1
http://www.hl7.org/implement/standards/product_brief.cfm?product_id=280

- HL7 Version 3 Standard: Security and Privacy Ontology, Release 1
Category: Privacy and Consent
Description: Names, defines, formally describes, and interrelates key security and privacy concepts within the scope of Healthcare Information Technology, including security policies, privacy policies, consent directives, resulting access control, and related ideas.
Link: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=348

- HL7 Healthcare (Security and Privacy) Access Control Catalog, Release 3
Category: Authorization

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Description: Enables trading partners to exchange interoperable role information in patient consent directives and trust policies, and to enable access control systems to enforce data segmentation. This standard is based on ASTM E 1986 roles and maps these to well understood healthcare information objects to create coded RBAC permissions, which can be shared with trading partners that require recipients to comply with the sender's access control policies. HL7 expects to publish the Healthcare Access Control Catalog in October 2016 as an update to the RBAC Catalog to include Attribute Based Access Control (ABAC) codes for clearances, which leverage the HL7 HCS security labels to enable data segmentation.

Link: http://gforge.hl7.org/gf/download/docmanfileversion/9149/14155/HL7%20Healthcare%20Access%20Control%20Catalog_v1.1_post-ballot%20reconciliation.docx

- HL7 Privacy, Access and Security Services (PASS) Access Control Services Conceptual Model, Release 1.0

  Category: Authorization

  Description: Describes the capabilities required to provide Access Control services to protected resources in a distributed healthcare environment. A pre-requisite to any Access Control activity is the management of Access Control policies. This document, which HL7 expects to publish in October 2016 as a normative standard, considers the behavior associated with the lifecycle of those policies.

  Link: http://gforge.hl7.org/gf/download/docmanfileversion/9344/14551/PASS%20Alpha%20-%20Access%20Control%20Conceptual%20Model%20Release%201.0%20-%20Ballot%20Final%20Content_Updated.docx

- ASTM E1384-07 (2013) Standard Practice for Content and Structure of the Electronic Health Record (EHR)

- ASTM E1714-07(2013) Standard Guide for Properties of a Universal Healthcare Identifier (UHID)

- ASTM E1762 – 95 (2013) Standard Guide for Electronic Authentication of Health Care Information

  Category: Authentication

  Description: This is a consensus standard on the design, implementation, and use of electronic signatures. It provides guidance for healthcare providers who are implementing electronic signature mechanisms.

  Link: http://www.astm.org/Standards/E1762.htm

- ASTM E1985-98(2013) Standard Guide for User Authentication and Authorization

- ASTM E1986 – 09 (2013) Standard Guide for Information Access Privileges to Health Information

  Category: Authorization

  Description: Covers the process of granting and maintaining access privileges to health information. It directly addresses the maintenance of confidentiality of personal, provider, and organizational data in the healthcare domain.

  Link: http://www.astm.org/Standards/E1986.htm

- ASTM E2017-99 (2010) Standard Guide for Amendments to Health Information

- ASTM E2147-01(2013) Standard Specification for Audit and Disclosure Logs for Use in Health Information Systems

- ASTM E2212-02a(2010) Standard Practice for Healthcare Certificate Policy

- ASTM E2553-07(2013) Standard Guide for Implementation of a Voluntary Universal Healthcare Identification System

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- ASTM E2595 - -07 (2013) Standard Guide for Privilege Management Infrastructure
  Category: Authorization
  Description: Defines interoperable mechanisms to manage privileges in a distributed environment. Supports policy-based access control (including role-, entity-, and contextual-based access control) including the application of policy constraints, patient-requested restrictions, and delegation.
  Link: https://www.astm.org/Standards/E2595.htm
- ISO/TS 14265:2011 Health informatics - Classification of purposes for processing personal health information
- ISO 17090-1:2013 Health informatics - Public Key Infrastructure - Part 1: Overview of digital certificate services
- ISO 17090-2:2015 Health informatics - Public key infrastructure -- Part 2: Certificate profile
- ISO 17090-3:2008 Health informatics - Public key infrastructure - Part 3: Policy management of certification authority
- ISO/IS 17090-4 Health informatics - Public key infrastructure-Part 4: Digital signatures for healthcare documents
- ISO/TS 17975:2015 Health informatics - Principles and data requirements for consent in the Collection, Use or Disclosure of personal health information
- ISO 21091: 2013 Health informatics - Directory services for healthcare providers, subjects of care and other entities
- ISO/TS 21298:2008 Health informatics -- Functional and structural roles

New Section Suggestions
- It is critical that systems have required functionality to support interoperability. The HL7 EHR System Functional Model is the most detailed and comprehensive Normative Standard addressing the creation (Origination) of electronic health information (EHI) as well as its maintenance for primary and secondary uses. The EHR Workgroup welcomes this increasing visibility for EHI Origination in the Functional Model and invites increasing collaboration on implementation guides and tools. We especially invite interest in advancing EHR reliability for accurate and authentic patient care information at origination and throughout its lifecycle, with integrity assured. Recognizing that the value of interoperability depends heavily on the quality of the source extends benefits to all stakeholders and end-uses, locally and through exchange, in direct care, public health reporting, and public policy support.

  To these ends, HL7 has developed and approved (by formal consensus) a suite of Functional Models (FMs) and Functional Profiles for Electronic Health Record (EHR) and Personal Health Record (PHR) systems. The FMs have been further recognized internationally as they have been approved by consensus of ISO National Member Bodies. The two Functional Models are now published as International Standards by both organizations:
  - 1) ISO/HL7 10781 EHR System Functional Model, Release 2, aka EHR-S FM (published by HL7 2014, ISO 2015) (see: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=269)

- 2) ISO/HL7 16527 PHR System Functional Model, Release 2, aka PHR-S FM (published by HL7 2014, ISO 2015) (see: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=88)

To enable interoperability as part of US Meaningful Use, we have developed and approved via consensus:

- 3) HL7 Meaningful Use Functional Profile for Stages 1&2 (published 2015), based on ISO/HL7 10781 EHR-S FM (see: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=409)

To enable interoperability for public/population health, we have developed (in collaboration with the US Centers for Disease Control and Prevention (CDC)) and approved via consensus:

- 4) HL7 Public Health Functional Profiles (published 2015), suite of nine (9) FPs for specific public health services/domain areas, based on ISO/HL7 10781 EHR-S FM (see: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=278)

To enable interoperability of EHR/PHR record content when implementing HL7 Fast Health Interoperable Resources (FHIR), we have developed and approved via consensus:

- 5) HL7 Record Lifecycle Event Implementation Guide, part of FHIR DSTU-2 (published September 2015), based on ISO/HL7 10781 EHR-S FM, Record Infrastructure Chapter, Record Entry Lifespan and Lifecycle (see: http://hl7.org/fhir/ehrsrle/ehrsrle.html)

Each of the Functional Profiles and the Functional Model support all EHR systems meeting a common set of conformance criteria that promote standardized collection, storage, and communication of structured and non-structured data. These profiles and the FM support enhanced interoperability. HL7 strongly supports the inclusion of these Functional Models/Profiles and the FHIR Implementation Guide (items 1-5 above). 10 HL7 suggests the inclusion of these Functional Models/Profiles and the FHIR Implementation Guide in a new category in the Advisory.